



CLINICAL LABORATORY BULLETIN May 2008

Web page: <http://health.utah.gov/lab/labimp>

❖ INTRODUCING

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NOTEWORTHY

✓ **New *Salmonella* reporting:** The Utah Public Health Laboratories will begin using the Modified Kauffman-White Scheme to report *Salmonella* isolates later this summer. For example: a report will include the common name - “*Salmonella enteritidis*” - and the Kauffman-White designation – D:[1],9,12,g,m. Some recently identified *Salmonella* isolates have no common name, only the new scientific designation. Once the lab’s computer system is updated, you should see this new system reflected in your laboratory reports.

✓ **Medicare not paying for mistakes:** Beginning October 1, 2008 hospitals may be denied payment for 8 secondary conditions that result following a medical error or improper care patients can reasonably expect to be avoided during their stay. The “list” includes incompatible blood administration, pressure ulcers, injuries after a fall, and nosocomial infections (infection acquired after admission). An article regarding this DRG (diagnosis-related groups) non-payment for non-performance can be found in the New England Journal of Medicine (Rosenthal MB> Nonpayment for performance? Medicare’s new reimbursement rule. *N Engl J Med.* 2007;357:1573-1575).

✓ **Freezing / thawing clinical specimens:**

Since pre-analytic problems cause more laboratory errors than analytic and post-analytic combined, consider these points for specimens that need to be frozen and /or thawed.

1. Follow the manufacturer’s instructions for freezing – liquid nitrogen for fast freezing, dry ice, additives, etc. Contact your reference lab if they fail to provide specific instructions.

Placing a plasma sample for coagulation tests in your refrigerator freezer before shipment will greatly alter the prothrombin time (PT) and probably other tests as well.

2. Generally you should thaw serum or plasma at room temperature. Be sure to carefully invert the thawed tube 10 to 20 times before running the test.

3. The American Association of Blood Banks (AABB) has procedures for thawing frozen blood components. They recommend fresh frozen plasma be thawed in a 30 to 37° C water bath. A microwave can be used in emergencies as long as it has been validated not to exceed temperature limits and not to damage plasma proteins.

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4. Be aware that specimens stored in -20° C frost-free freezers may experience freeze-thaw cycles which will affect their accuracy.

✓ **i-Stat PT compares to BCS analyzer:**

Researchers at the University Hospital in Geneva Switzerland tested 35 patients on varying oral anticoagulant dosage. Whole blood capillary samples were tested on the i-Stat analyzer (Abbott) and compared to plasma samples on the BCS analyzer with Innovin reagent (Dade Behring). The correlation coefficient was 0.95. Bias values were 0.04, 0.2 and -0.04 at INR (International Normalized Ratio) levels of 2.0, 2.5 and 3.5 respectfully.

Other point of care INR instruments available were not compared with either method.

✓ **Is e-mail your life?:** Gregg Gregory gives suggestions in the March 10, 2008 issue of *Advance* on how to optimize your efficiency as you deal with all those messages.

- *Schedule a time(s) to check your mail.

- *Check with the recipient before forwarding large attachments.

- *Protect privacy – use the “blind copy” section to send to multiple recipients.

- *Take a moment before pushing the “send” button. Once it is gone, you cannot get it back.

- *Be careful with the “reply to all” button. Be certain you know who “all” is and if “all” need to hear what you have to say.

- *Use “high priority” only when it is! (How often the STAT request is overused in the lab).

- *Read what you write again. Be clear. You don’t have verbal and non-verbal skills to help get your real meaning across.

- *(I would add) If you are not including the original message (reply feature), make certain the recipient knows what that original message was referring to.

✓ **Autoimmune Hepatitis:** Hepatitis means liver inflammation. We are familiar with viral hepatitis as well as hepatitis caused by alcohol

abuse. But the immune system may also destroy liver cells. About 0.7 persons per 100,000 will develop autoimmune hepatitis (AIH) this year. Most will be female with a high number from northern Europe. Symptoms are similar to infectious hepatitis. Antibodies are usually antinuclear, anti-smooth muscle, or anti-liver-kidney-microsomal. Diagnosis is based on ruling out the other causes and AIH is left. Confirmation testing and inflammation assessment can be done using a liver biopsy.

Treatment consists of anti-inflammatory agents such as steroids and azathioprine. In severe cases, liver transplant may be necessary.

✓ **Hemolysis affects coagulation testing:**

Researchers reported the results of adding lysed citrated blood (ranging from zero to 9.1 %) to 10 patient samples. The samples were then tested for prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen, and D-dimer. The Clinical Abstract report in the February 2008 CAP Today does not list the testing method, but references the research in the *Arch Pathol Lab Med.* 2006;130:181-184.

Researchers concluded there were significant increases in PT with 0.5 % and D-dimer at 2.7%; and significant decreases in aPTT and fibrinogen in samples with 0.9% lysate concentrations. The authors felt the variation from patient to patient was too great to recommend a lysis correction factor. They suggested quantifying free hemoglobin in a suspect samples and then recollecting if high.

✓ **Neonate testing – critical values:** If you are using adult critical values to interpret neonatal conditions, Maria Proytcheva, MD recommends you look at a study from Johns Hopkins Children’s Center. There appears to be no consensus on adult standards, let alone pediatric (including neonates). Dr. Proytcheva states the research finds little agreement among fellows, residents and attending physicians on what they thought “critical” to neonatal care.

CAP agreed when they evaluated the results of a Q Probe audit. Recommendations from the February 2008 CAP Today article is to meet with the clinicians in your facility often to decide what is critical for your patient population and how they want to be notified. Meet regularly to discuss changes in medical decision levels. Don't forget that critical usually means **immediately** life threatening.

✓ **Pipettes perform poorly in desert**

climates: ARTEL from Westbrook ME tested pipettes in Death Valley to determine the effect of dry and hot environments on pipetting. They found pipettes delivered up to 35% less volume in the desert. The researchers tried pre-wetting the pipet tips. That helped some, but most pipet systems still operated outside their specified tolerance limits.

While parts of Utah and surrounding desert states (AZ, NV, NM) experience dry heat in the range of Death Valley, other laboratories may experience accuracy problems without noticing. George Rodrigues, PhD and senior scientific manager for ARTEL states "Laboratories often experience changes in humidity and temperature throughout the course of a year, and data may be at risk".

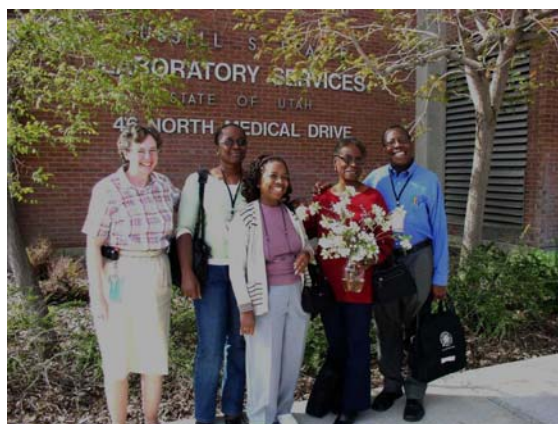
ARUP's website wins award: *ARUP Consult, The Physician's Guide to Laboratory Test Selection and Interpretation* was awarded the Gold 2007 eHealthcare Leadership Award for Best Design of a Physician/Clinician-Focused Web Site. They were picked from more than 1,100 entries. The website, updated every 8 weeks, currently has more than 1,500 tests categorized by disease-related topics. Clinicians can select from topics such as clinical background, diagnostic advice, suggested test ordering, and clinical decision-making algorithms. Also available are links to national guidelines and other references. The free service is available to healthcare professionals at www.arupconsult.com or m.arupconsult.com for mobile users.

"Winning may not be everything, but losing has little to recommend it."

**John D.
Rockefeller Jr.**

☆ Feature ☆

Barbados Public Health Laboratory (BPHL) and the Utah Public Health



Laboratories (UPHL) participate in the World Health Organization (WHO) Laboratory Twinning Initiative

Barbara Jepson welcomes Stephanie Sobers, Stephanie Hector, Marcia Miller and Edmund Blades (BPHL director) to Salt Lake City, Utah

June, 2007 found Patrick Luedtke, MD, UPHL Director and Barbara Jepson, MS, Microbiology Bureau Director on the beautiful island of Barbados visiting the BPHL. May 1,

2008 the administrative staff from the BPHL returned the visit.

Barbados is the farthest eastern Caribbean island. Located slightly north of the border between Venezuela and Guyana, they have close ties with South America. The 167 square mile island supports approximately 279,000 people. Tourism is their largest industry as the lovely beaches, outstanding hotels and cuisine attest. Formerly part of the British Commonwealth, they became an independent country in 1966. English is their native language. Education, through college, is free.

During the Barbadian's two-week visit the staff observed food and water microbiology; enteric bacteriology; mycobacteriology; molecular biology; and immunology testing at UPHL. They also visited the Department of Agriculture Laboratory; the local air monitoring station; the state's Epidemiology Bureau and spoke with a laboratory LIMS specialist. The group visited Primary Children's Medical Center to discuss the Vitek microbiology identification and susceptibility system. Edmund and Stephanie Hector accompanied the surveyor on a CLIA recertification survey. Marcia toured a clinical microbiology laboratory.



Barbadians visit with Dr. Gundlapalli at the Agriculture laboratory

Of course there was time in the evenings and on weekends to shop, tour ski resorts, visit Temple Square and attend a Tabernacle Choir

rehearsal. The laboratory hosted a Utah traditional potluck barbecue outside (on 1 of 2 mostly sunshiny days). The group and a few brave UPHL employees spent a memorable Saturday touring Antelope Island in the Great Salt Lake. Also included in the group's two-week visit was the groundbreaking ceremonies for the new UPHL in Taylorsville (scheduled to be completed in the summer of 2009).



Barbadians with Scott Becker (APHL) and Dr. Luedtke at the ground breaking ceremony

BPHL and UPHL have grown very close as we share common laboratory challenges, successes and ideas. What a great vehicle to foster idea exchanges and cooperation between countries!.

Thank you WHO!

**Equals
"1 million bicycles:
2 megacycles"**



CLIA BITS

ADDITIONAL WAIVED TESTS:

- Qualigen, Inc. Fast Check TSH (whole blood)
- Henry Schein One Step + Strep A Cassette
- Clarity MONO Rapid Test & Strep A Rapid Strip
- Bayer A1C Now + for Professional Use
- Abaxis Piccolo xpress Chemistry Analyzer (Liver Panel Plus Reagent Disc and Liver Panel Reagent Disc) and Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc) (Whole Blood) for **cholesterol**
- Abaxis Piccolo xpress Chemistry Analyzer (Liver Panel Plus) (Whole Blood) for **albumin, ALP, ALT, amylase, AST, total bilirubin, gamma glutamyl transferase (GGT), and total protein**
- Abaxis Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc and Lipid Panel Reagent Disc) for **HDL cholesterol and triglyceride**
- Abaxis Piccolo xpress Chemistry Analyzer (Lipid Panel Plus Reagent Disc) for **ALT, AST and glucose**
- Abaxis Piccolo Point of Care Chemistry Analyzer (Lipid Panel Plus Reagent Disc) for **HDL cholesterol and triglyceride**

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Assessing Job Applicants with Education Credentials from other Countries

To meet CLIA regulations, be certain you find the credentialing agency you use to translate the academic accomplishments of your applicant to their USA equivalent on the list of CMS “approved” credentials evaluators. Two agencies approve evaluators and are recognized by CLIA as acceptable.

Association of International Credentials Evaluators (AICE)

http://www.aice-eval.org/index_006.htm

National Association of Credential Evaluation Services (NACES)

<http://www.naces.org/members.htm>

Check the list each time you need an evaluation as agencies periodically drop and are added.

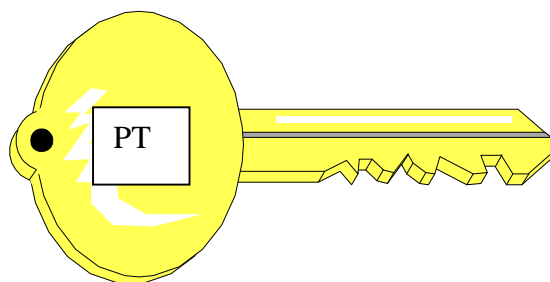
Quality Assessment Spotlight



The quality assurance officer (QA) received a call from a point of care nursing station. They were concerned that all of their patients were testing positive for a particular infectious disease test kit. Upon investigation, the QA officer discovered the external positive control was being used as a reagent in the testing process.

If it seems unbelievable, investigate, it probably is!

Kudos Danielle Laursen, Mountain Star, Quality Assurance



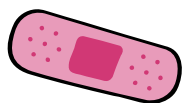
Proficiency Testing Referral

Karen Lusky interviewed several pathologists for an article in the March 2008 issue of CAP Today entitled “PT referral raising red flags

with CMS”. While many pathologists vented their frustration on a regulation with such a severe penalty, this problem is not new – just escalating. For what ever reason (more incidents or better detection), the number of cases are increasing.

The first two referral cases under the CLIA 88 amendments were identified shortly after the regulations were implemented in 1992. One case was discovered in Utah and one in California. Both cases went to court (to test the new regulation). CMS won. The penalties assigned to cheating on proficiency testing (PT) were written into the law by federal legislatures – not assigned by CMS in the law interpretation process of writing and approving regulations.

What about the patients? If your testing process isn’t good enough to send into a PT provider for grading, how is it good enough for your patients? There are minor penalties assigned to a facility that fails PT two of three times (such as stop testing the offending analyte, fix the problem, and pass two challenges). Cheating may result in loss of laboratory ownership and the ability of the director to direct any lab testing for 2 years. Is it worth it?



SAFETY

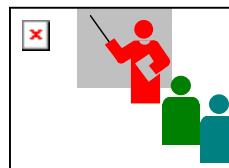
FDA Recall

December 20, 2007 – Class 1 Recall: AM2 PAT Inc. Pre-Filled Heparin Lock Flush Syringes and Normal Saline IV Flush Syringes (all lots and all sizes). These products are distributed under two brand names – Sierra Pre-Filled Inc. and B. Braun. CDC found some unopened syringes contaminated with *Serratia marcescens*. This bacteria can cause septicemia. CDC also received reports of infections associated with the Pre-Filled Normal Saline IV Flush syringes.

Ponderables:

Why are you IN a movie, but you’re ON TV?

CONTINUING EDUCATION



CDC Wet Workshop

Laboratory Identification of Pathogenic Molds
July 16-18, 2008 in Atlanta, Georgia

Registration deadline is June 25, 2008. Cost is \$245. Register at www.nltn.org/231-08.htm.
Course number is 510-231-08.

Understanding Our Universe

“It is well to remember that the entire universe, with one trifling exception, is composed of others.”

John Andrew Holmes